UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,463	11/23/2005	**Ying Zhang**	200507001-1	3795

40079 7590 06/26/2008

YUAN QING JIANG
P.O. BOX 61214
PALO ALTO, CA 94306

EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
06/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,463	ZHANG ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6,8-11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *8,10 and 11* is/are allowed.

6)☒ Claim(s) *4-6, 9, 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 03/18/08.

The amendment filed 03/18/08 affects the application, 10/538,463 as follows:

Claims 8-10 have been amended. Claims 1-3, 12, 13 have been canceled. Upon further consideration, it was determined that the indication of allowable subject matter in the prior office action mailed 10/19/07 was not appropriate. Consequently, the said allowable subject matter is withdrawn. Applicants' amendments have overcome the rejections made under 35 U.S.C. 112, first and second paragraphs. A new ground(s) rejection is made herein.

The responsive to applicants' amendments is contained herein below.

Claims 4-6, 8-11, 14 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for intensifying SOD activity or reducing MDA level of the skin or hair in a subject comprising administering to a subject a therapeutically effective amount of total triterpenoid sapogenins extracted from bamboo, wherein total triterpenoid sapogenins is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as a standard, said total triterpenoid sapogenins comprising 5-35% friedelin and 1-10% lupenone as determined by GC-MS to intensify SOD activity or to reduce MDA level of the skin or hair, wherein said

therapeutically effective amount of total triterpenoid sapogenins is administered externally onto the skin or hair in a daily cosmetic, does not reasonably provide enablement for protecting skin or hair from senescence comprising administering to a subject a therapeutically effective amount of said composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method of protecting skin or hair from senescence, comprising administering to a subject a therapeutically effective amount of total triterpenoid sapogenins extracted from bamboo, wherein total triterpenoid sapogenins is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as a standard, said total triterpenoid sapogenins comprising 5-35% friedelin and 1-10% lupenone as determined by GC-MS to intensify SOD activity or to reduce MDA

level of the skin or hair, wherein said therapeutically effective amount of total triterpenoid sapogenins is administered externally onto the skin or hair in a daily cosmetic.

The relative skill of those in the art: The relative skill of those in the art is high. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert protecting skin or hair from senescence by a therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on protecting skin or hair from senescence (which encompasses biological processes of living organism approaching an advanced age and involves the combination of processes of deterioration which follow the period of development of an organism) in a subject comprising administering to any subject an effective amount of the claimed composition.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses protecting skin or hair from senescence (which encompasses biological processes of living organism approaching an advanced age and involves the combination of processes of deterioration which follow the period of development of an organism) in a subject comprising administering to any subject an effective amount of a composition, which

are not known to have a single recognized cause. Applicant claims a method of protecting skin or hair from senescence in a subject comprising administering to said subject an effective amount of a given composition, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for protecting skin or hair from senescence, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the senescence of skin or hair (which encompasses biological processes of living organism approaching an advanced age and involves the combination of processes of deterioration which follow the period of development of an organism) and which are characterized as being numerous unpredictable ones, does not have a single recognized cause. It should be noted that the process of senescence is complex, and may derive from a variety of different mechanisms and exist for a variety of different reasons. Also, both genetic and environmental factors contribute to the process of senescence. In fact, the aforementioned senescence of skin or hair, are recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness which can be complicated by existing physical or medical conditions in the subject such as cardiovascular disease, cancer, arthritis, cataract, osteoporosis, type 2 diabetes, hypertension and Alzheimer's disease. These are only a few of the factors that promote senescence of skin or hair in a subject. Applicant has not provided a description as how any cause (like the aforementioned) can be prevented, much less a description of how the said conditions can be prevented.

Thus, the skilled artisan would view that the prevention of adverse effects (which is characterized as having many contributing factors and causes) in a patient by administering to said patient the specific compound and inhibitor herein, as being highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

Moreover, it is noted that the specification provides no working examples to the prevention of said adverse effects.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the prevention of adverse effects in a patient in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of protecting the skin or hair from senescence in any subject as recited in the instant claims suitable to practice the claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method with a reasonable expectation of success. Therefore, protecting the skin or hair from senescence in a subject by the said method is not enabled by the instant disclosure.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staack Reis Machado et al. (EP 1122259 A2) in view of Ohmoto et al. (Shoyakugaku Zasshi (1974), 28(1), pages 1-6, abstract Only).

In claim 4, applicant claims a method of extracting total triterpenoid sapogenins from bamboo comprising:

(a) selecting bamboo material from the group consisting of Phyllostachys, Bambusa and Dendrocalamus genus of Gramineae family;

(b) preparing bamboo shaving powder having a granularity from pole, branch, leaf, shoot, shoot sheath, root or a mixture of the bamboo material;

(c) extracting free triterpenoid sapogenins from the bamboo shaving powder by mixing the bamboo shaving powder with supercritical CO_2 fluid and an entrainer in the amount of 5 -15 % (v/v) of CO_2 until the free triterpenoid sapogenins is dissolved in the CO2 fluid at temperature 50 - 60 degree C and pressure 25 - 35 Mpa;

(d) separating total triterpenoid sapogenins from the CO_2 fluid containing free triterpenoid sapogenins by changing the temperature of the CO_2 fluid to 35 - 45 degree C and the pressure to 5 - 10 Mpa to gasify the CO2;

(e) collecting a composition comprising 10 - 90% total triterpenoid sapogenins, said total triterpenoid sapogenins comprising 5 - 35% friedelin and 1 - 10% lupenone. Claims 5-6 and 14 are drawn to the method of claim 4 further comprising extracting free triterpenoids sapogenins from the bamboo powder with recycled recycled CO_2 for given time, the use of specific entrainer including ethanol and the use of specific granularity.

Staack Reis Machado et al. disclose a method for extracting triterpenoids (including friedelin and related compounds) from the ceroid fraction of cork smoker wash solids comprising mixing the material with the supercritical CO_2 fluid, thereby making the low-polar substances of said material such as free triterpenoids dissolve in CO_2 fluid, wherein and the extraction temperature is between 30-50 °C and the pressure is between 4-40 Mpa (see abstract, example 1, claims). Staack Reis Machado et al. disclose that the pressure and temperature may be changed during the exraction, or may be constant, and carries out the separation at separation temperature between 20-120 °C and pressure between 40 Mpa and atmospheric pressure (see abstract, example 1, claims). Furthermore, Staack Reis Machado et al. disclose that the co-solvent can be ethanol (see claim 5).

The difference between applicant's claimed method and the method of Staack Reis Machado et al. is that Staack Reis Machado et al. do not extract their triterpenoids from the same plant (bamboo), as applicant. However, Staack Reis Machado et al. disclose that compounds including triterpenoids can be extracted from natural origins and that supercritical fluids can be

applied in the extraction of natural products (see page 2, section [0009]-[0011]). This implies that triterpenoids can be extracted or isolated from natural origins such as from plants (e.g. (bamboo plant).

Ohmoto et al. disclose a composition comprising triterpenoid sapogenins and related compounds that are extracted from bamboo (Arundinarieae) of Gramineae plants wherein said composition comprises friedelin, lupenone and other pentacyclic triterpenoids (see abstract). It should be noted that Arundinaria is a genus of bamboo commonly known as canes. Ohmoto et al. do not explicitly disclose the total % of triterpenoid sapogenins and the % of friedelin and lupenone in their composition. But, the silence of Ohmoto et al. does not mean that their composition does not contain the same said total % of triterpenoid sapogenins and % of friedelin and lupenone. Furthermore, it should be noted that Ohmoto et al.'s composition is obtained from the same source as applicant's composition and comprises the same components or substances (friedelin and lupenone) as applicant's composition and consequently may well have the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. anticipates the claims if their composition has the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. renders the claims as being obvious if the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in their composition is substantially close to the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in applicant's composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Staack Reis Machado et al. and Ohmoto et al., to have used the method of Staack Reis Machado et al. to extract triterpenoids from any plant such as bamboo in

order to use them to treat conditions such as rheumatoid diseases, based on factors such as availability, cost, convenience and/or need.

One having ordinary skill in the art would have been motivated in view of Staack Reis Machado et al. and Ohmoto et al., to use the method of Staack Reis Machado et al. to extract triterpenoids from any plant such as bamboo in order to use them to treat conditions such as rheumatoid diseases, based on factors such as availability, cost, convenience and/or need. It should be noted that a skilled artisan would be motivated to modify the physical parameters such as temperature, concentration, time and repetition or types of extractions in order to optimize the process conditions and physical variables such as amounts, % yield and/or purity of product (i.e., phytosterols). It should be noted that merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: The examiner has found claims 8, 10 and 11 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates a method of treating hypertension, comprising administering to a subject suffering from said hypertension a therapeutically effective amount of a specific triterpenoid sapogenins composition extracted from bamboo. The invention also relates to a method of in vitro inhibiting growth of specific cancer cells or tumor cells comprising treating the cancer cells or tumor cells with a therapeutically effective amount of a specific triterpenoid sapogenins composition extracted from bamboo. The prior art does not teach or suggest the method of the instant invention as set forth in claims 8, 10 and 11.

Response to Arguments

Applicant's arguments with respect to claims 4-6, 8-11, 14 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

June 16, 2008.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623